UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2021

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-39620

PRAXIS PRECISION MEDICINES, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**47-5195942**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
99 High Street, 30th Floor Boston, MA	**02110**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: 617-300-8460

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**PRAX**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of October 29, 2021, the registrant had 44,855,777 shares of common stock, $0.0001 par value per share, outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- the success, cost and timing of our product candidate development activities and clinical trials;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates;
- the ability to license additional intellectual property relating to our product candidates from third parties and to comply with our existing license agreements and collaboration agreements;
- the ability and willingness of our third-party research institution collaborators to continue research and development activities relating to our product candidates;
- our ability to commercialize our product candidates, if approved, in light of the intellectual property rights of others;
- our ability to obtain funding for our operations, including funding necessary to complete further development and, if approved, commercialization of our product candidates;
- the commercialization of our product candidates, if approved;
- our plans to research, develop and, if approved, commercialize our product candidates;
- future agreements with third parties in connection with the commercialization of our product candidates, if approved, and any other approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates, if approved;
- the pricing and reimbursement of our product candidates, if approved;
- regulatory developments in the United States and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and
- the effect of the COVID-19 pandemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to our ongoing and planned preclinical studies and clinical trials.

In some cases, you can identify forward-looking statements by terminology such as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause

actual results to differ materially from current expectations include, among other things, those listed under the section titled “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2020 and under the section titled "Risk Factors" in this Quarterly Report on Form 10-Q. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed with the Securities and Exchange Commission as exhibits hereto completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this Quarterly Report on Form 10-Q represent our views as of the date of this Quarterly Report on Form 10-Q. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from our own internal estimates and research as well as from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. While we are not aware of any misstatements regarding any third-party information presented in this Quarterly Report on Form 10-Q, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties and are subject to change based on various factors, including those discussed under the section titled “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2020 and elsewhere in this Quarterly Report on Form 10-Q.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

PRAXIS PRECISION MEDICINES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(Amounts in thousands, except share and per share data)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 165,679	$ 296,608
Marketable securities	148,691	—
Prepaid expenses and other current assets	4,969	5,718
Total current assets	319,339	302,326
Property and equipment, net	625	82
Operating lease right-of-use assets	4,028	754
Other non-current assets	416	15
Total assets	$ 324,408	$ 303,177
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 7,544	$ 4,088
Accrued expenses	16,529	10,869
Operating lease liabilities	681	763
Total current liabilities	24,754	15,720
Long-term liabilities:		
Non-current portion of operating lease liabilities	3,732	—
Total liabilities	28,486	15,720
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized and no shares issued or outstanding as of September 30, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value; 150,000,000 shares authorized; 44,784,071 shares issued and outstanding as of September 30, 2021, and 38,268,543 shares issued and outstanding as of December 31, 2020	5	4
Additional paid-in capital	553,975	437,007
Accumulated other comprehensive loss	(25)	—
Accumulated deficit	(258,033)	(149,554)
Total stockholders' equity	295,922	287,457
Total liabilities and stockholders' equity	$ 324,408	$ 303,177

The accompanying notes are an integral part of these condensed consolidated financial statements.

PRAXIS PRECISION MEDICINES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(Amounts in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 33,139	$ 12,786	$ 76,746	$ 28,704
General and administrative	11,634	3,431	31,929	7,552
Total operating expenses	44,773	16,217	108,675	36,256
Loss from operations	(44,773)	(16,217)	(108,675)	(36,256)
Other income:				
Other income, net	73	1	201	134
Total other income	73	1	201	134
Loss before income taxes	(44,700)	(16,216)	(108,474)	(36,122)
Benefit from (provision for) income taxes	(5)	—	(5)	8
Net loss	$ (44,705)	$ (16,216)	$ (108,479)	$ (36,114)
Accretion and cumulative dividends on redeemable convertible preferred stock	—	(3,943)	—	(8,046)
Gain on repurchase of redeemable convertible preferred stock	—	—	—	493
Net loss attributable to common stockholders	$ (44,705)	$ (20,159)	$ (108,479)	$ (43,667)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.00)	$ (12.10)	$ (2.61)	$ (26.53)
Weighted average common shares outstanding, basic and diluted	44,714,941	1,665,902	41,608,017	1,645,982

The accompanying notes are an integral part of these condensed consolidated financial statements.

PRAXIS PRECISION MEDICINES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

(Amounts in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss	$ (44,705)	$ (16,216)	$ (108,479)	$ (36,114)
Unrealized gains (losses) on marketable securities, net of tax	25	—	(25)	—
Comprehensive loss	$ (44,680)	$ (16,216)	$ (108,504)	$ (36,114)

The accompanying notes are an integral part of these condensed consolidated financial statements.

PRAXIS PRECISION MEDICINES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(Unaudited)

(Amounts in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance at December 31, 2020	38,268,543	$ 4	$ 437,007	$ (149,554)	$ —	$ 287,457
Stock-based compensation expense	—	—	4,666	—	—	4,666
Issuance of common stock upon exercise of stock options	352,506	—	851	—	—	851
Unrealized loss on marketable securities, net of tax	—	—	—	—	(86)	(86)
Net loss	—	—	—	(27,373)	—	(27,373)
Balance at March 31, 2021	38,621,049	$ 4	$ 442,524	$ (176,927)	$ (86)	$ 265,515
Stock-based compensation expense	—	—	5,400	—	—	5,400
Issuance of common stock from follow-on public offering, net of offering costs of $229	5,750,000	1	98,412	—	—	98,413
Issuance of common stock upon exercise of stock options	322,113	—	809	—	—	809
Change unrealized loss on marketable securities, net of tax	—	—	—	—	36	36
Net loss	—	—	—	(36,401)	—	(36,401)
Balance at June 30, 2021	44,693,162	$ 5	$ 547,145	$ (213,328)	$ (50)	$ 333,772
Stock-based compensation expense	—	—	6,521	—	—	6,521
Issuance of common stock upon exercise of stock options	90,909	—	309	—	—	309
Change unrealized loss on marketable securities, net of tax	—	—	—	—	25	25
Net loss	—	—	—	(44,705)	—	(44,705)
Balance at September 30, 2021	44,784,071	$ 5	$ 553,975	$ (258,033)	$ (25)	$ 295,922

The accompanying notes are an integral part of these condensed consolidated financial statements.

PRAXIS PRECISION MEDICINES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(Unaudited)

(Amounts in thousands, except share data)

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series B-1 Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Series C-1 Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2019	8,075,799	$ 9,932	14,913,704	$49,969	2,666,666	$10,431	9,805,827	$50,789	—	$ —	1,621,880	$ 1	$ —	$ (81,009)	$ —	$ (81,008)
Repurchase of Series C redeemable convertible preferred stock	—	—	—	—	—	—	(5,825,243)	(30,493)	—	—	—	—	—	493	—	493
Series C redeemable convertible preferred stock issuance costs	—	—	—	—	—	—	—	(37)	—	—	—	—	—	—	—	—
Vesting of restricted common stock awards	—	—	—	—	—	—	—	—	—	—	13,143	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	147	—	—	147
Accretion of redeemable convertible preferred stock to redemption value	—	160	—	890	—	199	—	815	—	—	—	—	(147)	(1,917)	—	(2,064)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(8,330)	—	(8,330)
Balance at March 31, 2020	8,075,799	$10,092	14,913,704	$50,859	2,666,666	$10,630	3,980,584	$21,074	—	$ —	1,635,023	$ 1	$ —	$ (90,763)	$ —	$ (90,762)
Issuance of Series C redeemable convertible preferred stock, net of issuance costs of $4	—	—	—	—	—	—	4,563,108	23,496	—	—	—	—	—	—	—	—
Vesting of restricted common stock awards	—	—	—	—	—	—	—	—	—	—	13,142	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	285	—	—	285
Accretion of redeemable convertible preferred stock to redemption value	—	162	—	890	—	198	—	789	—	—	—	—	(285)	(1,754)	—	(2,039)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(11,568)	—	(11,568)
Balance at June 30, 2020	8,075,799	$10,254	14,913,704	$51,749	2,666,666	$10,828	8,543,692	$45,359	—	$ —	1,648,165	$ 1	$ —	$ (104,085)	$ —	$ (104,084)
Issuance of Series C-1 redeemable convertible preferred stock, net of issuance costs of $154	—	—	—	—	—	—	—	—	19,444,453	110,096	—	—	—	—	—	—
Vesting of restricted common stock awards	—	—	—	—	—	—	—	—	—	—	13,142	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	953	—	—	953
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	—	—	—	—	11,628	—	27	—	—	27
Accretion of redeemable convertible preferred stock to redemption value	—	162	—	899	—	201	—	885	—	1,796	—	—	(980)	(2,963)	—	(3,943)
Net Loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(16,216)	—	(16,216)
Balance at September 30, 2020	8,075,799	$10,416	14,913,704	$52,648	2,666,666	$11,029	8,543,692	$46,244	19,444,453	$111,892	1,672,935	$ 1	$ —	$ (123,264)	$ —	$ (123,263)

The accompanying notes are an integral part of these condensed consolidated financial statements.

PRAXIS PRECISION MEDICINES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(Amounts in thousands)

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (108,479)	$ (36,114)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	89	30
Stock-based compensation expense	16,587	1,385
Non-cash operating lease expense	942	517
Amortization of premiums and discounts on marketable securities, net	1,454	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	749	(398)
Accounts payable	4,031	544
Accrued expenses	5,481	2,160
Operating lease liabilities	(566)	(515)
Other	15	(4)
Net cash used in operating activities	(79,697)	(32,395)
Cash flows from investing activities:		
Purchases of property and equipment	(519)	—
Purchases of marketable securities	(164,170)	—
Maturities of marketable securities	14,000	—
Net cash used in investing activities	(150,689)	—
Cash flows from financing activities:		
Proceeds from follow-on public offering, net of issuance costs	98,480	—
Payment of issuance costs for initial public offering and issuance of redeemable convertible preferred stock	(575)	(1,117)
Proceeds from exercise of options to purchase common stock	1,968	27
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	133,442
Repurchase of Series C redeemable convertible preferred stock	—	(30,000)
Net cash provided by financing activities	99,873	102,352
Decrease in cash, cash equivalents and restricted cash	(130,513)	69,957
Cash, cash equivalents and restricted cash, beginning of period	297,208	45,415
Cash, cash equivalents and restricted cash, end of period	$ 166,695	$ 115,372
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	165,679	114,772
Restricted cash	1,016	600
Total cash, cash equivalents and restricted cash	$ 166,695	$ 115,372
Supplemental disclosures of non-cash activities:		
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	$ 4,086	$ —
Deferred offering costs included in accrued expenses	$ 68	$ 925
Purchases of property and equipment included in accrued expenses	$ 116	$ —
Accretion of redeemable convertible preferred stock to redemption value	$ —	$ 8,046

The accompanying notes are an integral part of these condensed consolidated financial statements.

1. Nature of the Business

Praxis Precision Medicines, Inc. (“Praxis” or the “Company”) is a clinical-stage biopharmaceutical company translating genetic insights into the development of therapies for central nervous system (“CNS”) disorders characterized by neuronal imbalance. The Company has established a broad portfolio, including multiple disclosed programs across CNS disorders, including depression, epilepsy, movement disorders and pain syndromes, with three clinical-stage product candidates. The Company intends to develop differentiated therapies that can deliver long-term benefits to human health by meaningfully impacting patients and society. The Company’s most advanced programs, PRAX-114 and PRAX-944, are currently in Phase 2/3 and Phase 2 development, respectively. PRAX-114 is an extrasynaptic GABAA receptor preferring positive allosteric modulator currently being developed for the treatment of major depressive disorder and for the treatment of women with menopausal and mood symptoms. The Company plans to initiate Phase 2 trials of PRAX-114 in post-traumatic stress disorder and essential tremor ("ET") in the fourth quarter of 2021 and intends to disclose plans for a Phase 2b trial in women with menopausal and mood symptoms in the fourth quarter of 2021. PRAX-944 is a selective small molecule inhibitor of T-type calcium channels currently being developed for the treatment of ET. The Company plans to initiate a Phase 2 trial of PRAX-944 in Parkinson's disease in the first half of 2022. In addition, the Company completed a Phase 1 healthy volunteer trial of its third clinical program, PRAX-562, a persistent sodium current blocker, for the potential treatment of a broad range of rare CNS disorders, such as severe pediatric epilepsies and rare adult cephalgias. The Company plans to initiate a Phase 2 trial in rare adult cephalgias in the fourth quarter of 2021. In addition to the clinical programs, the Company has multiple disclosed preclinical and discovery product candidates in development for severe genetic epilepsies and multiple undisclosed preclinical and discovery product candidates for a range of CNS disorders.

Praxis was incorporated in 2015 and commenced operations in 2016. The Company has funded its operations primarily with proceeds from the issuance of convertible debt and redeemable convertible preferred stock, and from the sale of common stock through an initial public offering and a follow-on public offering. From inception through September 30, 2021, the Company raised $509.4 million in aggregate cash proceeds from these transactions, net of issuance costs.

In May 2021, the Company completed a follow-on public offering in which the Company issued and sold 5,750,000 shares of its common stock at a public offering price of $18.25 per share, including 750,000 shares of common stock issued and sold pursuant to the underwriters' exercise, in full, of their option to purchase additional shares of common stock, for aggregate gross proceeds of $104.9 million. The Company received approximately $98.4 million in net proceeds after deducting discounts, commissions and offering expenses payable by the Company.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including but not limited to, risks associated with completing preclinical studies and clinical trials, receiving regulatory approvals for product candidates, development by competitors of new biopharmaceutical products, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Programs currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales.

Liquidity

In accordance with the Financial Accounting Standards Board (“FASB”) Accounting Standards Update (“ASU”) 2014-15, *Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern (Subtopic 205-40)*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that these condensed consolidated financial statements are issued.

The Company has incurred recurring losses since its inception, including net losses of $108.5 million for the nine months ended September 30, 2021. In addition, as of September 30, 2021, the Company had an accumulated deficit of $258.0 million. The Company expects to continue to generate operating losses for the foreseeable future.

The Company expects that its cash, cash equivalents and marketable securities as of September 30, 2021 of $314.4 million will be sufficient to fund the operating expenses and capital expenditure requirements necessary to advance its research efforts and clinical trials for at least one year from the date of issuance of these condensed consolidated financial statements. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. There can be no assurance that the current operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and ASUs of the FASB.

The significant accounting policies used in preparation of these condensed consolidated financial statements for the three and nine months ended September 30, 2021 are consistent with those discussed in Note 2 to the consolidated financial statements included in the Company's 2020 Annual Report on Form 10-K, other than as noted below.

Unaudited Interim Condensed Consolidated Financial Information

The accompanying condensed consolidated balance sheet as of September 30, 2021, the condensed consolidated statements of operations for the three and nine months ended September 30, 2021 and 2020, the condensed consolidated statements of comprehensive loss for the three and nine months ended September 30, 2021 and 2020, the condensed consolidated statements of cash flows for the nine months ended September 30, 2021 and 2020 and the condensed consolidated statements of redeemable convertible preferred stock and stockholders' equity (deficit) for the three and nine months ended September 30, 2021 and 2020 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual consolidated financial statements, and in the opinion of management reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the Company's financial position as of September 30, 2021, the results of its operations for the three and nine months ended September 30, 2021 and 2020 and its cash flows for the nine months ended September 30, 2021 and 2020. Financial statement disclosures for the three and nine months ended September 30, 2021 and 2020 are condensed and do not include all disclosures required for an annual set of financial statements in accordance with GAAP.

The results for the three and nine months ended September 30, 2021 are not necessarily indicative of results to be expected for the year ended December 31, 2021, any other interim periods, or any future year or period.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, the accrual for research and development expense, stock-based compensation expense, and the valuation of equity awards prior to the Company's initial public offering. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ materially from those estimates.

Marketable Securities

The Company invests its excess cash in money market funds and debt instruments of the U.S. Treasury, financial institutions, corporations and U.S. government agencies with strong credit ratings and an investment grade rating at or above A-1 or P-1 by two of the three nationally recognized statistical rating organizations. The Company does not believe that it is exposed to more than a nominal amount of credit risk in its marketable securities. The Company has established guidelines relative to diversification and maturities that maintain safety and liquidity, and periodically reviews and modifies these guidelines to maximize trends in yields and interest rates without compromising safety and liquidity. The Company classifies its investments in debt instruments as available-for-sale. Available-for-sale investments are reported at fair value at each balance sheet date, and include any unrealized holding gains and losses in accumulated other comprehensive gain (loss), a component of stockholders' equity. Realized gains and losses are included in the Company's condensed consolidated statements of operations. All of the Company's available-for-sale securities are available for use in its current operations. As a result, the Company has categorized all of these securities as current assets even though the stated maturity of some individual securities may be one year or more beyond the balance sheet date.

The Company evaluates securities for impairment at the end of each reporting period. Impairment is evaluated considering numerous factors, and their relative significance varies depending on the situation. Factors considered include whether a decline in fair value below the amortized cost basis is due to credit-related factors or non-credit-related factors, the financial condition and near-term prospects of the Company, and the Company's intent and ability to hold the investment to allow for an anticipated recovery in fair value. A credit-related impairment is recognized as an allowance on the balance sheet with a corresponding adjustment to earnings. Any impairment that is not credit-related is recognized in other comprehensive (loss) income, net of applicable taxes unless deemed other than temporary.

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740)—Simplifying the Accounting for Income Taxes* ("ASU 2019-12"). The ASU simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in ASC 740, Income Taxes, related to the approach for allocating income tax expense or benefit for the year to continuing operations, discontinued operations, other comprehensive income, and other charges or credits recorded directly to shareholders' equity; the methodology for calculating income taxes in an interim period; and the recognition of deferred tax liabilities for outside basis differences. On January 1, 2021, the Company early adopted ASU 2019-12 on a prospective basis, with no material impact on its condensed consolidated financial statements and related disclosures.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326)—Measurement of Credit Losses on Financial Instruments,* which has been subsequently amended by ASU No. 2018-19, ASU No. 2019-04, ASU No. 2019-05, ASU No. 2019-10, ASU No. 2019-11 and ASU No. 2020-03 ("ASU 2016-13"). The provisions of ASU 2016-13 modify the impairment model to utilize an expected loss methodology in place of the currently used incurred loss methodology and require a consideration of a broader range of reasonable and supportable information to inform credit loss estimates. ASU 2016-13 is effective for the Company on January 1, 2023, with early adoption permitted. Given the Company will lose its emerging growth company status on December 31, 2021, it expects to reflect the adoption of this standard in its annual report on Form 10-K for the year ended December 31, 2021. The Company is evaluating the potential impact that this standard may have on its financial position and results of operations, but does not expect the impact to be significant.

3. Marketable Securities

The following is a summary of the Company's investment portfolio at September 30, 2021 (in thousands). The Company did not have any marketable securities as of December 31, 2020.

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Available-for-sale securities:				
Corporate debt securities	$ 51,642	$ 1	$ (10)	$ 51,633
Commercial paper	41,976	—	—	41,976
Debt securities issued by U.S. government agencies	12,156	6	—	12,162
Other debt securities	$ 6,428	$ —	$ (1)	6,427
Total securities with a maturity of one year or less	$ 112,202	$ 7	$ (11)	$ 112,198
Corporate debt securities	36,514	—	(21)	36,493
Total securities with a maturity of one to two years	$ 36,514	$ —	$ (21)	$ 36,493
Total available-for-sale securities	$ 148,716	$ 7	$ (32)	$ 148,691

As of September 30, 2021, the Company had 14 securities with a total fair market value of $87.5 million in an unrealized loss position. The Company believes that any unrealized losses associated with the decline in value of its securities is temporary and primarily related to the change in market interest rates since purchase, and believes that it is more likely than not that it will be able to hold its debt securities to maturity. Therefore, the Company anticipates a full recovery of the amortized cost basis of its debt securities at maturity.

Securities are evaluated for impairment at the end of each reporting period. The Company did not record any impairment related to its available-for-sale securities during the three and nine months ended September 30, 2021.

4. Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset in an orderly transaction between market participants at the measurement date. The Company categorizes financial assets measured at fair value based on a fair value hierarchy. The following fair value hierarchy is used to classify financial assets based on observable inputs and unobservable inputs used to value the financial assets:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical assets;
- Level 2: Quoted prices for similar assets in active markets, quoted prices in markets that are not active, or inputs which are unobservable, either directly or indirectly, for substantially the full term of the asset; or
- Level 3: Prices or valuation techniques that require inputs that are both significant to the valuation of the asset and unobservable.

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	As of September 30, 2021			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 151,452	$ —	$ —	$ 151,452
Marketable securities:				
Corporate debt securities	—	88,126	—	88,126
Commercial paper	—	41,976	—	41,976
Debt securities issued by U.S. government agencies	12,162	—	—	12,162
Other debt securities	—	6,427	—	6,427
	$ 163,614	$ 136,529	$ —	$ 300,143

	As of December 31, 2020			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 290,931	$ —	$ —	$ 290,931
	$ 290,931	$ —	$ —	$ 290,931

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Accrued external research and development expenses	$ 10,348	$ 4,206
Accrued personnel-related expenses	3,909	5,516
Accrued professional services	1,324	133
Accrued other	948	1,014
Total accrued expenses	$ 16,529	$ 10,869

6. Commitments and Contingencies

In May 2021, the Company entered into a sublease agreement for office space located in Boston, Massachusetts, which became the Company's corporate headquarters beginning on October 1, 2021. The sublease expires on January 31, 2026, with no option to renew or terminate early. The base rent increases by approximately 2% annually. The Company issued a letter of credit to the landlord for $0.4 million related to the security deposit, secured by restricted cash, which is reflected within other non-current assets on the accompanying condensed consolidated balance sheet as of September 30, 2021. This lease qualifies as an operating lease. At inception, the Company recorded an operating lease right-of-use asset and operating lease liability of $4.1 million. As of September 30, 2021, the Company had an operating lease right-of-use asset of $3.8 million, current operating lease liability of approximately $0.5 million, and non-current operating lease liability of approximately $3.7 million included in the condensed consolidated balance sheet.

Future lease payments under the non-cancellable sublease agreement as of September 30, 2021 were as follows (in thousands):

Year Ended December 31,	Future Lease Payments
2021	$ —
2022	1,160
2023	1,270
2024	1,296
2025	1,321
2026	110
Total future lease payments	$ 5,157
Less: interest	(942)
Present value of operating lease liabilities	$ 4,215

As of September 30, 2021, the remaining lease term and discount rate of the sublease agreement was 4.3 years and 9.0%, respectively.

In October 2018, the Company entered into a sublease agreement for office space located in Cambridge, Massachusetts that expires on December 31, 2021, with no option to renew or terminate early. The base rent increases by approximately 1% annually. The Company issued a letter of credit to the landlord for $0.6 million related to the security deposit, secured by restricted cash, which is reflected within prepaid expenses and other current assets on the accompanying condensed consolidated balance sheets as of September 30, 2021 and December 31, 2020, as the lease term expires less than twelve months from the condensed consolidated balance sheet dates. This lease qualifies as an operating lease.

7. Common Stock and Preferred Stock

Common Stock

As of September 30, 2021 and December 31, 2020, the authorized capital stock of the Company included 150,000,000 shares of common stock, $0.0001 par value.

As of September 30, 2021 and December 31, 2020, the Company did not hold any treasury shares.

Shares Reserved for Future Issuance

The Company has reserved the following shares of common stock for future issuance:

	September 30, 2021	December 31, 2020
Shares reserved for exercise of outstanding stock options	6,414,070	5,944,546
Shares reserved for future awards under the 2020 Stock Option and Incentive Plan	3,011,438	3,036,776
Shares reserved for future awards under the 2020 Employee Stock Purchase Plan	654,204	327,102
Shares reserved for vesting of restricted stock units	383,196	—
Total shares of authorized common stock reserved for future issuance	10,462,908	9,308,424

Preferred Stock

As of September 30, 2021 and December 31, 2020, the authorized capital stock of the Company included 10,000,000 shares of undesignated preferred stock, $0.0001 par value.

8. Stock-Based Compensation

2020 Stock Option and Incentive Plan

The total number of shares of common stock authorized for issuance under the 2020 Stock Option and Incentive Plan (the "2020 Plan") as of September 30, 2021 and December 31, 2020 was 5,184,455 shares and 3,271,028 shares, respectively.

2017 Stock Incentive Plan

The total number of shares of common stock authorized for issuance under the 2017 Stock Incentive Plan (the "2017 Plan") as of September 30, 2021 and December 31, 2020 was 5,937,763 shares. Any authorization to issue new options under the 2017 Plan was cancelled upon the effectiveness of the 2020 Plan and no further awards will be granted under the 2017 Plan.

2020 Employee Stock Purchase Plan

The total number of shares of common stock authorized for issuance under the 2020 Employee Stock Purchase Plan (the "2020 ESPP") as of September 30, 2021 and December 31, 2020 was 654,204 shares and 327,102 shares, respectively.

Restricted Stock Units

The following table summarizes the Company's restricted stock unit activity:

	Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2020	—	$ —
Issued	403,113	46.57
Vested	—	—
Forfeited	(19,917)	46.35
Unvested as of September 30, 2021	383,196	$ 46.58

Stock Options

The following table summarizes the Company's stock option activity:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
			(In years)	(In thousands)
Outstanding as of December 31, 2020	5,944,546	$ 7.47		
Granted	1,644,153	43.26		
Exercised	(765,528)	2.57		$ 18,009
Cancelled or Forfeited	(409,101)	14.94		
Outstanding as of September 30, 2021	6,414,070	$ 16.75	8.80	$ 54,154
Exercisable as of September 30, 2021	1,702,574	$ 6.17	8.23	$ 21,152
Vested and expected to vest as of September 30, 2021	6,414,070	$ 16.75	8.80	$ 54,154

The aggregate intrinsic value of stock options outstanding, exercisable, and vested and expected to vest is calculated as the difference between the exercise price of the underlying stock options and the estimated fair value of the Company's common stock for those stock options that had exercise prices lower than the estimated fair value of the Company's common stock at September 30, 2021. The aggregate intrinsic value of stock options exercised is calculated as the difference between the exercise price of the underlying stock options and the estimated fair value of the Company's common stock on the date of exercise for those stock options that had exercise prices lower than the estimated fair value of the Company's common stock on the exercise date.

Stock Option Valuation

The weighted-average assumptions that the Company used in the Black-Scholes option pricing model to determine the grant-date fair value of stock options granted to employees and non-employees on the date of grant were as follows for the three and nine months ended September 30, 2021:

	Three Months Ended September 30,	Nine Months Ended September 30,
	2021	2021
Risk-free interest rate	1.01 %	0.77 %
Expected term (in years)	6.00	6.10
Expected volatility	85.98 %	85.60 %
Expected dividend yield	— %	— %

The weighted-average grant-date fair value of the Company's stock options granted during the three and nine months ended September 30, 2021 was $13.45 per share and $30.91 per share, respectively.

Stock-Based Compensation

Stock-based compensation expense was allocated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ 2,787	$ 384	$ 7,136	$ 639
General and administrative	3,734	569	9,451	746
Total stock-based compensation expense	$ 6,521	$ 953	$ 16,587	$ 1,385

As of September 30, 2021, total unrecognized compensation expense related to unvested stock-based awards was $75.2 million, which is expected to be recognized over a weighted-average period of 2.85 years.

9. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator:				
Net loss	$ (44,705)	$ (16,216)	$ (108,479)	$ (36,114)
Accretion and cumulative dividends on redeemable convertible preferred stock	—	(3,943)	—	(8,046)
Gain on repurchase of redeemable convertible preferred stock	—	—	—	493
Net loss attributable to common stockholders	$ (44,705)	$ (20,159)	$ (108,479)	$ (43,667)
Denominator:				
Weighted average common shares outstanding, basic and diluted	44,714,941	1,665,902	41,608,017	1,645,982
Net loss per share attributable to common stockholders, basic and diluted	$ (1.00)	$ (12.10)	$ (2.61)	$ (26.53)

The following potential shares of common stock, presented based on amounts outstanding at each period end, were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have been anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Outstanding stock options	6,414,070	5,814,944	6,414,070	5,814,944
Unvested restricted common stock and restricted stock units	383,196	8,763	383,196	8,763
Series A redeemable convertible preferred stock	—	3,773,820	—	3,773,820
Series B redeemable convertible preferred stock	—	6,969,173	—	6,969,173
Series B-1 redeemable convertible preferred stock	—	1,246,133	—	1,246,133
Series C redeemable convertible preferred stock	—	3,992,463	—	3,992,463
Series C-1 redeemable convertible preferred stock	—	9,086,388	—	9,086,388
	6,797,266	30,891,684	6,797,266	30,891,684

The shares of common stock issuable upon conversion of the redeemable convertible preferred stock for the three and nine months ended September 30, 2020 assumed automatic conversion in the event of a qualified public offering.

10. Related Party Transactions

On September 11, 2019, the Company entered into a Cooperation and License Agreement (the “License Agreement”) with RogCon Inc. (“RogCon”). Under the License Agreement, RogCon granted to the Company an exclusive, worldwide license under RogCon’s intellectual property to research, develop and commercialize products for the treatment of all forms of epilepsy and/or neurodevelopmental disorders in each case caused by any mutation of the SCN2A gene. Pursuant to the terms of the License Agreement, the Company will conduct, at its own cost and expense, the research and development activities assigned to it under the associated research plan. In addition, the Company is responsible for reimbursing RogCon for any costs associated with research and development activities RogCon performs at the request of the Company. One of the founders of RogCon became the Company’s General Counsel in June 2020. The Company continues to reimburse RogCon for its out-of-pocket costs incurred for activities performed under the License Agreement. Expenses incurred during all periods presented were not material. As of September 30, 2021, the Company had accrued expenses of $0.3 million due to RogCon under the License Agreement.

11. Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the condensed consolidated financial statements to provide additional evidence for certain estimates or to identify matters that require additional disclosure. The Company has concluded that no subsequent events have occurred that require disclosure.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission, or SEC, on March 17, 2021. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2020 and set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company translating genetic insights into the development of therapies for central nervous system, or CNS, disorders characterized by neuronal imbalance. Normal brain function requires a delicate balance of excitation and inhibition in neuronal circuits, which, when dysregulated, leads to abnormal function and disease. We are applying insights from genetic epilepsies to broader neurological and psychiatric disorders, using our understanding of shared biological targets and circuits in the brain. We apply a deliberate and pragmatic precision approach, leveraging a suite of translational tools including novel transgenic and predictive translational animal models and electrophysiology markers, to enable an efficient path to proof-of-concept in patients. Through this approach, we have established a broad portfolio, including multiple disclosed programs across CNS disorders, including depression, epilepsy, movement disorders and pain syndromes, with three clinical-stage product candidates. We expect multiple topline clinical trial readouts from all three programs in the next year and anticipate the launch of a new clinical development program in the next year. We intend to develop differentiated therapies that can deliver long-term benefits to human health by meaningfully impacting patients and society.

Our most advanced clinical program, PRAX-114, is an extrasynaptic GABAA receptor preferring positive allosteric modulator, or PAM, for the treatment of patients suffering from major depressive disorder, or MDD, and
for the treatment of women with menopausal and mood symptoms. We completed a multi-cohort, three-part Phase 2a clinical trial in Australia for PRAX-114, in which Parts A and C of the trial treated patients with MDD while Part B focused on patients with perimenopausal depression, or PMD. For all parts of the trial, PRAX-114 was generally well-tolerated. In Parts A and C, we observed marked improvements in depression scores in MDD patients within two weeks of treatment that were maintained throughout the treatment period. In Part B, we observed improvements in both menopausal and mood symptoms, with mean decreases from baseline at Day 15 of 60% in frequency of moderate-to-severe hot flashes, 68% in the total score of the Perimenopausal Depression Questionnaire, 47% in the Hamilton Depression Rating Scale total score, 65% in the Hamilton Anxiety Rating Scale total score, and 40% in the total score of the Symptoms of Depression Questionnaire, with values trending toward baseline following discontinuation of PRAX-114. We expect to disclose plans for the Phase 2b study in the fourth quarter of 2021.

Our second clinical program, PRAX-944, is a potentially differentiated selective small molecule inhibitor of T-type calcium channels for the treatment of ET. We are currently conducting a Phase 2a proof-of-concept, open-label trial in ET patients. Preliminary site data from six participants in the low dose cohort showed tremor reduction, which compares favorably to the standard of care agents and historical placebo response. Based on the observed safety profile in the healthy volunteer titration study and the safety and preliminary efficacy data in ET participants administered up to 40mg daily, we added a second cohort to the ongoing ET Phase 2a trial where patients will be titrated to a dose of up to 120mg/day of PRAX-944. We expect preliminary open-label safety, tolerability and efficacy data from the second dose cohort in the Phase 2a trial in the fourth quarter of 2021, followed by topline data in the first half of 2022, which is expected to include data from the randomized withdrawal phase of the study. We also completed dosing in a two-part Phase 1 study to explore a faster titration regimen, which is designed to evaluate the safety, tolerability and PK of titrating PRAX-944 up to 120 mg in a 10-day regimen in participants aged 18 to 54 years (Part A) and 55 to 75 years (Part B). In addition, we initiated the PRAX-944 Phase 2b Essential1 Study for treatment of ET and expect topline results in the second half of 2022. The Essential1 Study is a placebo-controlled, dose-ranging clinical trial designed to evaluate the safety, tolerability and efficacy of PRAX-944 at 20, 60 or 120 mg per day. We also intend to initiate a Phase 2 trial to evaluate the safety, PK and efficacy of PRAX-944 as a non-dopaminergic treatment for the motor symptoms of Parkinson's disease in the first half of 2022.

Our most advanced rare disease product candidate and third clinical program, PRAX-562, is the first selective persistent sodium current blocker in development for the treatment of a broad range of rare, devastating CNS disorders, such as rare adult cephalgias and severe pediatric epilepsies. We completed the dosing and safety follow-up period for the single ascending dose and multiple ascending dose cohorts up to 150 mg and 120 mg, respectively, in a Phase 1 healthy volunteer study. PRAX-562 was well-tolerated, with no clinically significant safety findings. In this study, we used auditory steady state response, or ASSR, as an exploratory electroencephalogram, or EEG, biomarker to determine the doses required to achieve pharmacological blockade of persistent sodium current, which we believe is a potential indicator of efficacy in patients. We observed dose-related changes and a reduction in ASSR of greater than 50% after 14 days with daily dosing, as compared to baseline. Based on the observed signal in the ASSR marker in the Phase 1 study, we have started dosing patients in the United States in a Phase 1, placebo-controlled, two-cohort EEG study to validate the observed signal, and we expect topline data in the first half of 2022. The study is intended to evaluate ASSR as a biomarker for the PRAX-562 program to further support selection of therapeutic dose levels in Phase 2 studies.

We intend to initiate the first proof-of-concept trial of PRAX-562 in patients with rare adult cephalgias, including Short-lasting Unilateral Neuralgiform headache attacks with Conjunctival injection and Tearing, Short-lasting Unilateral Neuralgiform headache with Autonomic symptoms, and Trigeminal Neuralgia in the fourth quarter of 2021. We also plan to initiate a Phase 2 trial for treatment of developmental epileptic encephalopathies, or DEEs, in the first half of 2022. The FDA has granted both rare pediatric disease and orphan drug designations for PRAX-562 for the treatment of SCN2A and SCN8A developmental epileptic encephalopathies, or SCN2A-DEE and SCN8A-DEE, respectively.

In addition to our clinical programs, we have multiple disclosed preclinical and discovery product candidates in development for severe genetic epilepsies and multiple undisclosed preclinical and discovery product candidates for a range of CNS disorders. Our most advanced preclinical stage program is PRAX-222, an antisense oligonucleotide, or ASO, designed to decrease the expression levels of the protein encoded by the gene SCN2A in patients with gain-of-function mutations in SCN2A causing developmental epileptic encephalopathy. We completed the Investigational New Drug enabling toxicology study for PRAX-222 and plan to initiate regulatory submissions in order to begin a Phase 1/2 trial for treatment of SCN2A-DEE in the first half of 2022. The FDA has granted both rare pediatric disease and orphan drug designations for PRAX-222 for the treatment of SCN2A-DEE. We have one disclosed discovery program in development for KCNT1 related epilepsy, and in March 2021 we entered into an innovative research collaboration with The Florey Institute of Neuroscience and Mental Health to develop three additional novel ASOs for the treatment of patients with severe genetic epilepsies, including a novel approach targeting SCN2A loss-of-function mutations.

We were incorporated in 2015 and commenced operations in 2016. Since inception, we have devoted substantially all of our resources to developing our preclinical and clinical product candidates, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. We employ a “virtual” research and development model, relying heavily upon external consultants, collaborators and contract research organizations to conduct our preclinical and clinical activities. Since inception, we have financed our operations primarily with proceeds from the issuances of convertible debt, redeemable convertible preferred stock, and common stock from our initial public offering, or IPO, in October 2020 and follow-on public offering in May 2021.

On May 18, 2021, we completed a follow-on public offering in which we issued and sold 5,750,000 shares of our common stock at a public offering price of $18.25 per share, including 750,000 shares of common stock issued and sold pursuant to the underwriters' exercise, in full, of their option to purchase additional shares of common stock, for aggregate gross proceeds of $104.9 million. We received approximately $98.4 million in net proceeds after deducting discounts, commissions, and offering expenses payable by us.

We are a development stage company and we have not generated any revenue from product sales, and do not expect to do so for several years, if at all. All of our programs are still in preclinical and clinical development. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates, if approved. We have incurred recurring operating losses since inception, including a net loss of $108.5 million for the nine months ended September 30, 2021. As of September 30, 2021, we had an accumulated deficit of $258.0 million. We expect to incur significant expenses and operating losses for the foreseeable future as we expand our research and development activities. In addition, our losses from operations may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and

development activities. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- advance our lead product candidates, PRAX-114 and PRAX-944, to and through late stage clinical trials;
- advance our PRAX-562 product candidate to Phase 2 clinical trials;
- advance our preclinical programs to clinical trials;
- further invest in our pipeline;
- further invest in our manufacturing capabilities;
- seek regulatory approval for our investigational medicines;
- maintain, expand, protect and defend our intellectual property portfolio;
- acquire or in-license technology;
- secure facilities to support continued growth in our research, development and commercialization efforts;
- increase our headcount to support our development efforts and to expand our clinical development team;
- incur additional costs and general and administrative headcount growth associated with our continued operations as a public company; and
- incur additional costs as a public company as we transition out of emerging growth company and smaller reporting company status at the end of 2021.

In addition, as we progress toward potential marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of September 30, 2021, we had cash, cash equivalents and marketable securities of $314.4 million. We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2023. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "—Liquidity and Capital Resources."

COVID-19 Business Update

In light of the ongoing COVID-19 pandemic, we have implemented business continuity plans designed to address and mitigate the impact of the COVID-19 pandemic on our employees and our business, including our preclinical studies and clinical trials. We are continuing to operate during this period and have taken measures to secure our research and development activities. While we are experiencing limited financial impacts at this time, given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic, our business, financial condition and results of operations could be

materially adversely affected. We continue to closely monitor the COVID-19 pandemic as we evolve our business continuity plans, clinical development plans and response strategy.

In addition, while we have taken and are continuing to take steps to mitigate against possible delays, our planned clinical trials may be affected by the COVID-19 pandemic, including (i) delays or difficulties in enrolling and retaining patients in our planned clinical trials, including patients that may not be able or willing to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services; (ii) delays or difficulties in clinical site initiation, including difficulties in recruiting and retaining clinical site investigators and clinical site staff; (iii) diversion or prioritization of healthcare resources away from the conduct of clinical trials and towards the COVID-19 pandemic, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials, and because, who, as healthcare providers, may have heightened exposure to COVID-19 and adversely impact our clinical trial operations; (iv) interruption of our future clinical supply chain or key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal, state/provincial or municipal governments, employers and others; and (v) limitations in outsourced third-party resources that would otherwise be focused on the conduct of our planned clinical trials, including because of sickness of third-party personnel or their families, or the desire of third-party personnel to avoid contact with large groups of people.

Financial Operations Overview

Revenue

We have not generated any revenue since inception and do not expect to generate any revenue from the sale of products for several years, if at all. If our development efforts for our current or future product candidates are successful and result in marketing approval or collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from collaboration or license agreements that we may enter into with third parties.

Operating Expenses

Research and Development Expenses

The nature of our business and primary focus of our activities generate a significant amount of research and development costs. Research and development expenses represent costs incurred by us for the following:

- costs to develop our portfolio;
- discovery efforts leading to development candidates;
- clinical development costs for our programs; and
- costs to develop our manufacturing technology and infrastructure.

The costs above comprise the following categories:

- personnel-related expenses, including salaries, benefits and stock-based compensation expense;
- expenses incurred under agreements with third parties, such as consultants, investigative sites and contract research organizations, that conduct our preclinical and clinical studies and in-licensing arrangements;
- costs incurred to maintain compliance with regulatory requirements;
- costs incurred with third-party contract development and manufacturing organizations to acquire, develop and manufacture materials for preclinical and clinical studies; and
- depreciation, amortization and other direct and allocated expenses, including rent, insurance and other operating costs, incurred as a result of our research and development activities.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors and our clinical investigative sites. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our consolidated balance sheets as prepaid

expenses or accrued research and development expenses. Non-refundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized, even when there is no alternative future use for the research and development. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

A significant portion of our research and development costs have been external costs. We track direct external research and development expenses to specific programs upon commencement. Due to the number of ongoing programs and our ability to use resources across several projects, indirect or shared operating costs incurred for our research and development programs, such as personnel, facility costs and certain consulting costs, are not recorded or maintained on a program-specific basis.

Our major programs, PRAX-114, PRAX-944 and PRAX-562, are those for which we have initiated clinical activities. Our discovery-stage programs are those which are at an earlier point in the development process. The following table reflects our research and development expenses, including direct program-specific expenses summarized by major program, discovery-stage program costs and indirect or shared operating costs recognized as research and development expenses during each period presented (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
PRAX-114	$ 8,776	$ 4,077	$ 18,567	$ 9,137
PRAX-944	5,682	1,707	10,015	3,284
PRAX-562	3,104	885	9,256	2,527
Discovery-stage programs	5,099	2,154	12,689	4,050
Personnel-related (including stock-based compensation)	8,334	3,098	21,584	7,443
Other indirect research and development expenses	2,144	865	4,635	2,263
Total research and development expenses	$ 33,139	$ 12,786	$ 76,746	$ 28,704

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to increase in the foreseeable future as we advance our product candidates through the development phase, and as we continue to discover and develop additional product candidates, build manufacturing capabilities and expand into additional therapeutic areas.

At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales or licensing of our product candidates. This is due to the numerous risks and uncertainties associated with drug development, including the uncertainty of:

- our ability to add and retain key research and development personnel;
- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to successfully complete clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the U.S. Food and Drug Administration, or FDA, or any comparable foreign regulatory authority;
- our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize, our product candidates;
- our successful enrollment in and completion of clinical trials;

- the costs associated with the development of any additional product candidates we identify in-house or acquire through collaborations;
- our ability to discover, develop and utilize biomarkers to demonstrate target engagement, pathway engagement and the impact on disease progression of our product candidates;
- our ability to establish and maintain agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidates are approved;
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder;
- our ability to obtain and maintain patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates if and when approved;
- our receipt of marketing approvals from applicable regulatory authorities;
- our ability to commercialize products, if and when approved, whether alone or in collaboration with others; and
- the continued acceptable safety profiles of the product candidates following approval.

A change in any of these variables with respect to the development of any of our product candidates would significantly change the costs, timing and viability associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect, or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time to complete our clinical development activities. We may never obtain regulatory approval for any of our product candidates. Drug commercialization will take several years and millions of dollars in development costs.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including salaries, benefits and stock-based compensation, for personnel in our executive, finance, legal, commercial and administrative functions. General and administrative expenses also include legal fees relating to corporate matters; professional fees for accounting, auditing, tax and administrative consulting services; insurance costs; administrative travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for office rent and other operating costs. These costs relate to the operation of the business, unrelated to the research and development function, or any individual program. Costs to secure and defend our intellectual property, or IP, are expensed as incurred and are classified as general and administrative expenses.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support the expected growth in our research and development activities and the potential commercialization of our product candidates. We also expect to incur increased expenses associated with being a public company, particularly when we are no longer an emerging growth company or a smaller company, including increased costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs and investor and public relations costs. We also expect to incur additional IP-related expenses as we file patent applications to protect innovations arising from our research and development activities.

Other Income

Other Income, Net

Other income, net consists of interest income from our cash, cash equivalents and marketable securities and amortization of investment premiums and discounts.

Income Taxes

Since our inception, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or for our earned research and development tax credits due to our uncertainty of realizing a benefit from those items. Income taxes are determined at the applicable tax rates adjusted for non-deductible expenses, research and development tax credits and other permanent differences. Our income tax provision may be significantly affected by changes to our estimates. The income tax benefit (provision) for the three and nine months ended September 30, 2021 and 2020 was not material.

Results of Operations

Comparison of the Three Months Ended September 30, 2021 and 2020

The following table summarizes our consolidated statements of operations for each period presented (in thousands):

	Three Months Ended September 30,		Change
	2021	2020	
Operating expenses:			
Research and development	$ 33,139	$ 12,786	$ 20,353
General and administrative	11,634	3,431	8,203
Total operating expenses	44,773	16,217	28,556
Loss from operations	(44,773)	(16,217)	(28,556)
Total other income:			
Other income, net	73	1	72
Total other income	73	1	72
Loss before income taxes	(44,700)	(16,216)	(28,484)
Provision for income taxes	(5)	—	(5)
Net loss	$ (44,705)	$ (16,216)	$ (28,489)

Research and Development Expense

The following table summarizes our research and development expenses for each period presented, along with the changes in those items (in thousands):

	Three Months Ended September 30,		Change
	2021	2020	
PRAX-114	$ 8,776	$ 4,077	$ 4,699
PRAX-944	5,682	1,707	3,975
PRAX-562	3,104	885	2,219
Discovery-stage programs	5,099	2,154	2,945
Personnel-related (including stock-based compensation)	8,334	3,098	5,236
Other indirect research and development expenses	2,144	865	1,279
Total research and development expenses	$ 33,139	$ 12,786	$ 20,353

Research and development expenses increased approximately $20.4 million from approximately $12.8 million for the three months ended September 30, 2020 to $33.1 million for the three months ended September 30, 2021. The increase in research and development expenses was primarily attributable to the following:

- $5.2 million increase in personnel-related costs due to increased headcount, including an increase of $2.4 million in stock-based compensation expense;
- $4.7 million increase in expense related to our PRAX-114 program, driven by an increase in clinical-related and toxicology spend for our Phase 2/3 clinical trial for this program;

- $4.0 million increase in expense related to our PRAX-944 program, driven primarily by an increase in toxicology and clinical-related spend;
- $2.9 million increase in expense related to our discovery-stage programs, primarily driven by an increase in preclinical activities for such programs;
- $2.2 million increase in expense related to our PRAX-562 program, primarily driven by an increase in spend to support our upcoming clinical trails; and
- $1.3 million increase in other indirect research and development expenses, driven by an increase in facility and other allocated overhead costs primarily attributable to increased research and development headcount and our new office location, as well as an increase in technology spend.

General and Administrative Expense

General and administrative expenses increased $8.2 million from $3.4 million for the three months ended September 30, 2020 to $11.6 million for the three months ended September 30, 2021. The increase in general and administrative expenses was primarily attributable to the following:

- $4.7 million increase in personnel-related costs, primarily driven by increased headcount, including an increase of $3.2 million in stock-based compensation expense;
- $1.8 million increase in professional fees, including $1.0 million of increased commercial-related spend to support assessments of our clinical-stage programs, a $0.3 million increase in general and administrative infrastructure costs and a $0.3 million increase in audit and legal fees; and
- $1.7 million increase in other general and administrative expenses, including a $1.1 million increase in insurance and related costs, primarily due to becoming a public company, and a $0.2 million increase in technology related costs.

Other Income

Other income for the three months ended September 30, 2021 and 2020, comprised of interest income on our cash, cash equivalents and marketable securities and investment premium and discount amortization, was not material.

Comparison of the Nine Months Ended September 30, 2021 and 2020

The following table summarizes our consolidated statements of operations for each period presented (in thousands):

	Nine Months Ended September 30,		Change
	2021	2020	
Operating expenses:			
Research and development	$ 76,746	$ 28,704	$ 48,042
General and administrative	31,929	7,552	24,377
Total operating expenses	108,675	36,256	72,419
Loss from operations	(108,675)	(36,256)	(72,419)
Total other income:			
Other income, net	201	134	67
Total other income	201	134	67
Loss before income taxes	(108,474)	(36,122)	(72,352)
Benefit from (provision for) income taxes	(5)	8	(13)
Net loss	$ (108,479)	$ (36,114)	$ (72,365)

Research and Development Expense

The following table summarizes our research and development expenses for each period presented, along with the changes in those items (in thousands):

	Nine Months Ended September 30,		Change
	2021	2020	
PRAX-114	$ 18,567	$ 9,137	$ 9,430
PRAX-944	10,015	3,284	6,731
PRAX-562	9,256	2,527	6,729
Discovery-stage programs	12,689	4,050	8,639
Personnel-related (including stock-based compensation)	21,584	7,443	14,141
Other indirect research and development expenses	4,635	2,263	2,372
Total research and development expenses	$ 76,746	$ 28,704	$ 48,042

Research and development expenses increased approximately $48.0 million from $28.7 million for the nine months ended September 30, 2020 to $76.7 million for the nine months ended September 30, 2021. The increase in research and development expenses was primarily attributable to the following:

- $14.1 million increase in personnel-related costs primarily due to increased headcount, including an increase of $6.5 million in stock-based compensation expense;
- $9.4 million increase in expense related to our PRAX-114 program, driven by an increase in toxicology and clinical-related spend for our Phase 2/3 clinical trial for this program;
- $8.6 million increase in expense related to our discovery-stage programs, primarily driven by an increase in preclinical activities for such programs;
- $6.7 million increase in expense related to our PRAX-944 program, driven primarily by an increase in toxicology and clinical-related spend;
- $6.7 million increase in expense related to our PRAX-562 program, primarily driven by an increase in toxicology and clinical-related spend; and
- $2.4 million increase in other indirect research and development expenses, driven by an increase in facility and other allocated overhead costs primarily attributable to increased research and development headcount, as well as an increase in technology spend.

General and Administrative Expense

General and administrative expenses increased approximately $24.4 million from $7.6 million for the nine months ended September 30, 2020 to $31.9 million for the nine months ended September 30, 2021. The increase in general and administrative expenses was primarily attributable to the following:

- $13.1 million increase in personnel-related costs, primarily driven by increased headcount, including an increase of $8.7 million in stock-based compensation expense;
- $6.3 million increase in professional fees, including $3.5 million of increased commercial-related spend to support assessments of our clinical-stage programs, a $1.1 million increase in audit and legal fees and a $0.9 million increase in general and administrative infrastructure costs; and
- $4.9 million increase in other general and administrative expenses, including a $3.2 million increase in insurance and related costs due to becoming a public company, a $0.7 million increase in donations and sponsorships and a $0.5 million increase in technology spend.

Other Income

Other income for the nine months ended September 30, 2021 and 2020, comprised of interest income on our cash, cash equivalents and marketable securities and investment premium and discount amortization, was not material.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant losses in each period. We have not yet commercialized any of our product candidates, which are in various phases of preclinical and clinical development, and we do not expect to generate revenue from sales of any products for several years, if at all.

To date, we have financed our operations primarily with proceeds from the sale and issuance of our redeemable convertible preferred stock, the sale and issuance of convertible debt, and the sale and issuance of common stock in our IPO and follow-on public offering. From inception through September 30, 2021, we have raised $509.4 million in aggregate cash proceeds from these transactions, net of issuance costs. As of September 30, 2021, we had cash, cash equivalents and marketable securities of $314.4 million.

Historical Cash Flows

The following table provides information regarding our cash flows for each period presented (in thousands):

	Nine Months Ended September 30,	
	2021	2020
Net cash (used in) provided by:		
Operating activities	$ (79,697)	$ (32,395)
Investing activities	(150,689)	—
Financing activities	99,873	102,352
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (130,513)	$ 69,957

Operating Activities

Our cash flows from operating activities are greatly influenced by our use of cash for operating expenses and working capital requirements to support our business. We have historically experienced negative cash flows from operating activities as we have invested in developing our portfolio, drug discovery efforts and related infrastructure. The cash used in operating activities resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital, which are primarily the result of increased expenses and timing of vendor payments.

During the nine months ended September 30, 2021, net cash used in operating activities of $79.7 million was primarily due to our $108.5 million net loss, partially offset by $9.7 million in changes in operating assets and liabilities and $19.1 million of non-cash charges primarily related to stock-based compensation.

During the nine months ended September 30, 2020, net cash used in operating activities of $32.4 million was primarily due to our $36.1 million net loss, partially offset by $1.8 million in changes in operating assets and liabilities and $1.9 million of non-cash charges.

Investing Activities

During the nine months ended September 30, 2021, net cash used in investing activities of $150.7 million primarily related to the purchase of marketable securities, partially offset by the maturities of marketable securities. There were no cash flows from investing activities during the nine months ended September 30, 2020.

Financing Activities

During the nine months ended September 30, 2021, net cash provided by financing activities of $99.9 million consisted of net proceeds from our follow-on public offering of $98.5 million and net proceeds from the exercise of stock options of $2.0 million, partially offset by the payment of issuance costs for our IPO.

During the nine months ended September 30, 2020, net cash provided by financing activities of $102.4 million consisted of proceeds from the issuance of Series C-1 redeemable convertible preferred stock and exercise of stock options, partially offset by cash paid for the repurchase of our Series C redeemable convertible preferred stock and payment of issuance costs.

Plan of Operation and Future Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing research and development activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. In addition, we expect to incur additional costs associated with operating as a public company and as we transition from being an emerging growth company and a smaller reporting company. As a result, we expect to incur substantial operating losses and negative operating cash flows for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- advance the clinical development of our PRAX-114, PRAX-944 and PRAX-562 product candidates;
- advance the development of any additional product candidates;
- conduct research and continue preclinical development of potential product candidates;
- make strategic investments in manufacturing capabilities;
- maintain our current intellectual property portfolio and opportunistically acquire complementary intellectual property;
- seek to obtain regulatory approvals for our product candidates;
- potentially establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts and to support our operations as a public company; and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges.

We are unable to estimate the exact amount of our working capital requirements, but based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2023. However, we have based this estimate on assumptions that may prove to be wrong and we could exhaust our capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with product development, and because the extent to which we may enter into collaborations with third parties for the development of our product candidates is unknown, we may incorrectly estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our funding requirements and timing and amount of our operating expenditures will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of preclinical studies and clinical trials for our programs and product candidates;
- the number and characteristics of programs and technologies that we develop or may in-license;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;

- the costs necessary to obtain regulatory approvals, if any, for products in the United States and other jurisdictions, and the costs of post-marketing studies that could be required by regulatory authorities in jurisdictions where approval is obtained;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the continuation of our existing licensing arrangements and entry into new collaborations and licensing arrangements;
- the costs we incur in maintaining business operations;
- the costs associated with being a public company;
- the revenue, if any, received from commercial sales of any product candidates for which we receive marketing approval;
- the effect of competing technological and market developments;
- the impact of any business interruptions to our operations or to those of our manufacturers, suppliers or other vendors resulting from the COVID-19 pandemic or similar public health crisis; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates, although we currently have no commitments or agreements to complete any such acquisitions or investments in businesses.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not currently have any committed external source of funds. Market volatility resulting from the COVID-19 pandemic or other factors could also adversely impact our ability to access capital as and when needed. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of holders of our common stock. Additional debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially result in dilution to the holders of our common stock.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates to third parties that we would otherwise prefer to develop and market ourselves.

Contractual Obligations

As of September 30, 2021, there have been no significant changes to our contractual obligations from those described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Contractual Obligations and Commitments” included in our Annual Report on Form 10-K filed with the SEC on March 17, 2021, other than our new sublease agreement entered into in May 2021 for office space in Boston, Massachusetts. The space is being used as our new corporate headquarters as of October 1, 2021 and the sublease expires on January 31, 2026, with no option to renew or terminate early. The base rent increases by 2% annually. Starting in January 2022, we are obligated to pay $5.2 million in total future lease payments over the remaining term of the lease.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no changes to our critical accounting policies from those described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Significant Judgments and Estimates" included in our Annual Report on Form 10-K filed with the SEC on March 17, 2021.

JOBS Act and Emerging Growth Company Status

In April 2012, the JOBS Act was enacted. As an emerging growth company, or EGC, under the JOBS Act, we may delay the adoption of certain accounting standards until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for EGCs include presentation of only two years of audited financial statements in a registration statement for an initial public offering, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation and less extensive disclosure about our executive compensation arrangements. Additionally, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of the extended transition period and, therefore, while we are an EGC we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not EGCs, unless we choose to early adopt a new or revised accounting standard.

We will remain an emerging growth company until December 31, 2021.

Recently Issued Accounting Pronouncements

We have reviewed all recently issued standards and have determined that, other than as disclosed in Note 2 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, such standards will not have a material impact on our condensed consolidated financial statements or do not otherwise apply to our current operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Reserved.

Item 4. Controls and Procedures.

Management's Evaluation of Our Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2021. Based on the evaluation of our disclosure controls and procedures as of September 30, 2021, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

As of the date of this Quarterly Report on Form 10-Q, we are not party to any material legal matters or claims. We may become party to legal matters and claims arising in the ordinary course of business. We cannot predict the outcome of any such legal matters or claims, and despite the potential outcomes, the existence thereof may have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

The risk factor set forth below updates, and should be read in conjunction with, the risk factors previously disclosed in the section entitled "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on March 17, 2021.

If we encounter difficulties enrolling patients in our future clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We have and may in the future experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion.

Patient enrollment is affected by many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- in the case clinical trials focused on rare disease, the small size of the patient population and the potential of a patient being undiagnosed or misdiagnosed;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications that we are investigating;
- the impacts of the COVID-19 pandemic on clinical trial sites, personnel and patient travel (see —Business interruptions resulting from COVID-19 or a similar pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide may adversely affect our business);
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials altogether. Delays in patient enrollment may result in increased costs, affect the timing or outcome of the planned clinical trials, product candidate development and approval process and jeopardize our ability to seek and obtain the regulatory approval required to commence product sales and generate revenue, which could prevent completion of these trials, adversely affect our ability to advance the development of our product candidates, cause the value of our company to decline and limit our ability to obtain additional financing if needed.

We are also required to register certain clinical trials and post the results of completed clinical trials on a government-sponsored database, such as www.ClinicalTrials.gov in the United States, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Business interruptions resulting from COVID-19 or a similar pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide may adversely affect our business.

If a pandemic, epidemic or outbreak of an infectious disease occurs in the United States or worldwide our business may be adversely affected. In December 2019, a novel strain of coronavirus named SARS-CoV-2 was identified in Wuhan, China. This virus continues to spread globally, including in the United States and the disease it causes, COVID-19, has been declared a pandemic by the World Health Organization. The COVID-19 pandemic has impacted the global economy and may impact our operations, including the potential interruption of our clinical trial activities, regulatory reviews and our supply chain. Furthermore, the spread of the virus may affect the operations of key governmental agencies, such as the FDA, which may delay the development or approval process for our product candidates.

The COVID-19 pandemic has and may in the future delay enrollment in our clinical trials due to prioritization of hospital resources or patients being either unwilling to enroll in our trials or unable to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results and could delay our ability to obtain regulatory approval and commercialize our product candidates. For example, we had previously observed delays in our trial enrollment in Australia for our PRAX-944 Phase 2a trial due to stringent COVID-19 lockdown restrictions. While we didn't experience a material impact on this trial from the delay in enrollment, we cannot predict the scope and severity of potential shutdowns or disruptions of businesses due to COVID-19 in the future.

The spread of COVID-19 may also result in the inability of our suppliers to deliver components or raw materials on a timely basis or at all. Three vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020 and early 2021, and more are likely to be authorized in the coming months. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Such events may result in a period of business disruption, and in reduced operations, or doctors and medical providers may be unwilling to participate in our clinical trials, any of which could materially affect our business, financial condition and results of operations.

We continue to closely monitor the COVID-19 pandemic as we evolve our business continuity plans, clinical development plans and response strategy. The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the novel coronavirus and the actions to contain the coronavirus or treat its impact, among others. At present, we are not experiencing significant impact or delays from the COVID-19 pandemic on our business, operations and, if approved, commercialization plans. In addition, we have taken steps to mitigate against COVID-19 pandemic-related delays, and may take additional measures, intended to help minimize the risk of the virus to our employees, including temporarily requiring all employees to work remotely, suspending all non-essential travel worldwide for our employees, and discouraging employee attendance at industry events and in-person work-related meetings, which could negatively affect our business.

While we have taken and are continuing to take steps to mitigate against possible delays, our planned clinical trials may be affected by the COVID-19 pandemic, including (i) delays or difficulties in enrolling and retaining patients in our planned clinical trials, including patients that may not be able or willing to comply with clinical trial protocols if

quarantines impede patient movement or interrupt healthcare services; (ii) delays or difficulties in clinical site initiation, including difficulties in recruiting and retaining clinical site investigators and clinical site staff; (iii) diversion or prioritization of healthcare resources away from the conduct of clinical trials and towards the COVID-19 pandemic, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials, and because, who, as healthcare providers, may have heightened exposure to COVID-19 and adversely impact our clinical trial operations; (iv) interruption of our future clinical supply chain or key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal, state/provincial or municipal governments, employers and others; and (v) limitations in outsourced third-party resources that would otherwise be focused on the conduct of our planned clinical trials, including because of sickness of third-party personnel or their families, or the desire of third-party personnel to avoid contact with large groups of people. A significant outbreak of other infectious diseases in the future also could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations.

We will no longer be an "emerging growth company" or a "smaller reporting company" and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies will no longer apply to us.

We are currently an emerging growth company but because as of June 30, 2021, the market value of our common stock that was held by non-affiliates exceeded $700 million, we be a large-accelerated filer and will no longer qualify for such status commencing December 3, 2021. As a result, we will be subject to certain disclosure requirements that are applicable to other public companies that have not been applicable to us as an emerging growth company. These requirements include:

- compliance with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- compliance with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- full disclosure obligations regarding executive compensation; and
- compliance with the requirements of holding a nonbinding advisory vote on executive compensation and

We are also currently a smaller reporting company, but based on the market value of our common stock that was held by non-affiliates as of June 30, 2021, we have determined that we will no longer be a smaller reporting company as of January 1, 2022. However, for so long as we remain a smaller reporting company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not smaller reporting companies. Similar to emerging growth companies, smaller reporting companies are able to provide simplified executive compensation disclosure and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information or risk factors. As of January 1, 2022, we will no longer be able to rely on these reduced requirements.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds from Public Offering of Common Stock

In October 2020, we completed the initial public offering of our common stock, or IPO, pursuant to which we issued and sold 11,500,000 shares of our common stock at a price to the public of $19.00 per share. We received aggregate gross proceeds from our IPO of approximately $218.5 million, or aggregate net cash proceeds of approximately $200.3 million after deducting underwriting discounts and commissions and offering expenses.

All of the shares issued and sold in the IPO were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No. 333-249074), which was declared effective by the Securities and Exchange Commission, or the SEC, on October 15, 2020. There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on October 16, 2020.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None

Item 6. Exhibits.

Exhibit Number	Description
10.1	Retention Incentive Award Letter Agreement dated August 30, 2021, by and between Praxis Precision Medicines, Inc. and Bernard Ravina (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-39620) filed on August 30, 2021).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** The certifications furnished in Exhibit 32.1 hereto are deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

PRAXIS PRECISION MEDICINES, INC.

Date: November 3, 2021

By: /s/ Marcio Souza

Marcio Souza

Chief Executive Officer and Director (Principal Executive Officer)

Date: November 3, 2021

By: /s/ Timothy Kelly

Timothy Kelly

Chief Financial Officer (Principal Financial Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Marcio Souza, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Praxis Precision Medicines, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2021

By: /s/ MARCIO SOUZA
Marcio Souza
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Timothy Kelly, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Praxis Precision Medicines, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2021

By: /s/ TIMOTHY KELLY
Timothy Kelly
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Praxis Precision Medicines, Inc. (the "Company") for the quarter ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of their knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 3, 2021

By: /s/ MARCIO SOUZA
Marcio Souza
Chief Executive Officer
(Principal Executive Officer)

Date: November 3, 2021

By: /s/ TIMOTHY KELLY
Timothy Kelly
Chief Financial Officer
(Principal Financial Officer)